

- B3
15. (Amended) An immunogenic composition comprising a peptide consisting essentially of at least one amino acid sequence of *S. mutans* glucosyltransferase comprising an amino acid selected from the group consisting of aspartate 562, aspartate 567, histidine 561, tryptophan 491, glutamate 489, [an equivalent of aspartate 562, an equivalent of aspartate 567, an equivalent of histidine 561, an equivalent of tryptophan 491, an equivalent of glutamate 489,] and combinations thereof, and which is of sufficient length to raise an immune response in a mammal to whom it is administered.

REMARKS

Rejection of Claims 1, 4-5, 7-11, 15 and 17 Under 35 U.S.C. §112, Second Paragraph

Claims 1, 4-5, 7-11, 15 and 17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner states that the claims are indefinite because there is no defined specific amino acid sequence in the claims. Claims 1, 5 and 15 have been amended to recite that the glucosyltransferase is an *S. mutans* glucosyltransferase.

The Examiner also states that the claims are indefinite for using the term "an equivalent". Applicants clearly define "an equivalent" in the Specification, for example, at page 8, lines 18-26 and 31-34, and page 9, lines 1-8, as "residues present at equivalent sites (positions) in other *mutans* streptococcal GTFs (see, for example, Table 1)." The Specification further provides that these equivalent residues can be identified, for example, by aligning the amino acid sequences of other streptococcal GTFs based on homology to *S. mutans* GTF-B using methods known in the art (Specification page 8, lines 22-25). However, to expedite prosecution, the term "an equivalent" has been cancelled. Thus, the claims, as amended, even more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Objections Under 37 C.F.R. §1.75

Claims 15-17 are objected to under 37 C.F.R. §1.75 as being substantial duplicates of Claims 1, 2 and 4, respectively. Applicants respectfully note that Claims 1-2 and 4 recite "a vaccine composition" and Claims 15-17 recite "an immunogenic composition". The Specification (page 7, lines 23-26 and 32-33, and page 8, lines 1-2) provides definitions of these

terms which indicate that they are not coextensive. A vaccine composition “protects the immunized mammal against subsequent challenge by the immunizing agent or an immunologically cross-reactive agent”, while an immunogenic composition “may or may not protect the immunized mammal against subsequent challenge with the immunizing agent”. Thus, Applicants respectfully submit that Claims 15-17 are properly submitted along with Claims 1, 2 and 4 as varying in scope. Reconsideration and withdrawal of the objection are respectfully requested.

Reference Cited in Information Disclosure Statement

The Examiner states that U.S. application No. 08/967,573 cited on the 1449 form in the Information Disclosure Statement filed on August 23, 1999 has not been considered because no copy of the application was provided. Applicants note that 37 C.F.R. §1.98(a)(2)(iii) states that an Information Disclosure Statement must include a legible copy of each reference, “except that no copy of a U.S. patent application need be included”. Thus, Applicants are submitting a 1449 form herewith listing U.S. application No. 08/967,573 as reference AR, and Applicants respectfully request that the Examiner consider this reference and initial and return the 1449 form as evidence thereof.

Rejection of Claims 1-4 and 15-17 Under 35 U.S.C. §102(b)

Claims 1-4 and 15-17 are rejected under 35 U.S.C. §102(b) as being anticipated by Shiroza *et al.* (*J. Bacteriol.* 169:4263-4270 (1987)). The Examiner states that Shiroza *et al.* teach a polypeptide sequence which is 100% identical to the polypeptide sequence of SEQ ID NO:1 and SEQ ID NO: 3 of the instant application.

Applicants respectfully traverse this rejection. Shiroza *et al.* teach the entire sequence of the *S. mutans* GTF-B gene and corresponding protein. In the instant Specification, at page 9, lines 10-11, it is stated that useful peptides “will be less than the complete amino acid sequence of the intact GTF enzyme.” The Specification further states that the peptide will typically be between 5 and 21 amino acids in length (page 9, lines 11-13). Shiroza *et al.* do not provide any teaching or suggestion of peptides which are less than the full length of the GTF-B protein. More importantly, Shiroza *et al.* do not teach or suggest a vaccine or immunogenic composition of any type, but rather a mere protein sequence. Thus, Shiroza *et al.* do not anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-11 and 15-17 Under 35 U.S.C. §103(a)

Claims 1-11 and 15-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Shiroza *et al.* and Taubman *et al.* (U.S. Patent 5,686,075). The Examiner states that Shiroza *et al.* do not expressly teach a composition comprising multivalent polypeptides, but that Taubman *et al.* teach multicomponent and multivalent peptide compositions from glucosyltransferase. The Examiner concludes that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to covalently link the peptide of Shiroza *et al.* to a multivalent peptide composition as taught by Taubman *et al.* because of the known benefit of providing effective vaccine capabilities.

As stated above, Applicants reiterate that Shiroza *et al.* do not teach or suggest vaccine compositions or immunogenic compositions of any kind, and also do not teach or suggest the specific peptide portions recited in the instant claims. Taubman *et al.* do not remedy these defects, as Taubman *et al.* do not teach or suggest the specific peptide portions of the instant claims. Thus, the present invention is not obvious in light of the cited references. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (781) 861-6240.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Lisa M. Treannie
Lisa M. Treannie
Registration No. 41,368
Telephone (781) 861-6240
Facsimile (781) 861-9540

Lexington, Massachusetts 02421-4799
Dated: September 14, 2000